UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RUBEN WILLS, Plaintiff vs. MICROGENICS CORPORATION, ET AL., Defendants	Hon. Brian M. Cogan CASE 1:20-cv-04432-BMC-VMS **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT MICROGENICS CORPORATION'S MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT**

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I. INTRODUCTION

Based on a preliminary drug screen, the New York Department of Corrections and Community Supervision ("DOCCS") allegedly disciplined Plaintiff Ruben Wills for drug use during his incarceration. Plaintiff insists he was not using illicit drugs, and because DOCCS performed his drug screen using a urinalysis analyzer supplied by Defendant Microgenics Corporation, he blames Microgenics for the discipline DOCCS meted out.

In his Second Amended Complaint (the "Complaint"), Plaintiff alleges that Microgenics negligently caused his allegedly inaccurate drug screen. The Complaint is facially deficient, however, and Microgenics moves to dismiss Plaintiff's claim for two reasons:

First, the Complaint fails to plausibly allege that Microgenics owed Plaintiff a duty. Plaintiff claims a duty arose out of Microgenics' contract to supply analyzers and related products and services to DOCCS. But Plaintiff has no relationship with Microgenics, and under New York law, Microgenics' contractual undertaking to DOCCS did not give rise to a tort duty to Plaintiff.

Second, even if Plaintiff had adequately alleged a duty of care, the Complaint fails to plausibly allege that Microgenics breached any purported duty.

II. FACTUAL BACKGROUND

A. Plaintiff's incarceration

From July 2018 through August 2019, Plaintiff was incarcerated at Lincoln Correctional Facility. Compl. [ECF 25] ¶¶ 83, 115. Plaintiff claims he was transferred from Hudson Correctional Facility to Lincoln in July 2018 following his receipt of a Temporary Work Release. *Id.* ¶ 83.

B. DOCCS's drug-of-abuse screening procedures for inmates

DOCCS has determined that the "use by inmates of illicit drugs and alcohol presents a serious threat to the safety and security of a correctional facility." DOCCS Directive No. 4937 [Ex.

1[1]] at 1.[2] To address the threat, DOCCS employs "[a]ggressive and consistent urinalysis testing" as "one of many components of a program to ensure a drug-free environment within the Department's facilities." *Id.*

To conduct its aggressive urinalysis testing, DOCCS personnel obtain drug-of-abuse urine samples from inmates after escorting them to "the facility infirmary, clinic or other appropriate area." 7 NYCRR § 1020.4(d)(1). During the sample-collection process, DOCCS personnel are required to ask each inmate if he or she "has been taking any medication in the past month." 7 NYCRR § 1020.4(d)(2).

For DOCCS facilities equipped with urinalysis apparatuses, DOCCS personnel perform the urinalysis drug screens at the facility. 7 NYCRR § 1020.4(f)(1). The DOCCS employees who perform the drug screens must "be appropriately trained in the use of the testing apparatus and shall precisely follow procedures recommended by the manufacturer for the operation of the testing apparatus." 7 NYCRR § 1020.4(f)(1)(iii).

When an initial screen returns a positive result, a "second test shall be performed on the same sample." 7 NYCRR § 1020.4(f)(1)(iv). If the second test is also positive, "the individual performing the test shall cause a misbehavior report to be issued." *Id.*

As to any inmate who receives a positive urine drug screen and who also reported taking medication at the time the sample was obtained, DOCCS must conduct an "inquiry . . . to medical personnel as to what medications the inmate has received in the past month which may lead to a positive result." 7 NYCRR § 1020.4(d)(2).

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[1] All exhibits are attached to the contemporaneously filed Declaration of Christopher R. Carton.

[2] The Court may consider DOCCS directives at the Rule 12 stage. *E.g.*, *Young v. Corcoran*, 164 F. Supp. 3d 419, 421 (W.D.N.Y. 2016).

Prior to imposing discipline for drug use, DOCCS holds a hearing. 7 NYCRR § 253.6. The inmate may present a defense by, for example, explaining the positive drug screen, challenging the drug-screen procedures, and contesting whether the screen was duly authorized. *Lahey v. Kelly*, 71 N.Y.2d 135, 144 (1987). The inmate has the right to submit evidence. 7 NYCRR § 253.6(c).

C. DOCCS's chosen method for *inmate* drug-of-abuse screening

DOCCS personnel conduct approximately 340,000 drug-of-abuse urine "scans" per year across fifty-two locations. Contract No. CC161458 [Ex. 2], App. C, at 25.[3] To perform the scans, DOCCS uses "reagent tests." *Id.* That method, also referred to as the "immunoassay" method, "does not measure the amount of drugs in the urine directly, but instead measures the reaction of an enzyme to a specified drug." *Lahey v. Kelly*, 71 N.Y.2d 135, 140 (1987).

DOCCS has known for at least thirty-five years that immunoassay manufacturers consider positive drug-screen results to be preliminary and recommend confirming such results by an alternative scientific method, such as gas chromatography-mass spectrometry. *See Peranzo v. Coughlin*, 608 F. Supp. 1504, 1514 (S.D.N.Y. 1985) (discussing recommendations from a DOCCS immunoassay supplier that "positive results be confirmed by any of several chromatographic procedures"). Indeed, outside of the prison context, DOCCS uses those alternative methods. For instance, when a parolee screens positive for drug use via immunoassay, DOCCS requires a confirmation test "using the Gas Chromatography/Mass Spectrometry methodology to provide for a greater margin of accuracy." DOCCS Directive No. 9432 [Ex. 3] at 3. And when screening its own employees, DOCCS insists that *both* the initial *and* the confirmatory tests are conducted "by

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[3] The contract is integral to the Complaint, *see* Compl. ¶¶ 43–49, and may be considered at the Rule 12 stage, *Goel* v. *Bunge*, *Ltd*., 820 F.3d 554, 559 (2d Cir. 2016); *Interpharm, Inc. v. Wells Fargo Bank, Nat'l Ass'n*, 655 F.3d 136, 141 (2d Cir. 2011).

gas chromatography with mass spectrometry or an equivalent scientifically accepted method that provides quantitative data." DOCCS Directive No. 2115 [Ex. 4] at 6.

When screening prison inmates, however, DOCCS historically has not confirmed preliminary positive results through chromatographic procedures. *E.g.*, DOCCS Directive No. 4937 [Ex. 1] at 5.

D. Microgenics' supply of drug-screen equipment to DOCCS

In September 2018, DOCCS hired Microgenics to supply Indiko Plus urinalysis analyzers to its fifty-two correctional facilities. Compl. ¶ 43. The Indiko Plus is a 510(k)-cleared medical device and is manufactured by Microgenics' corporate affiliate Thermo Fisher Scientific Oy, the product's 510(k) applicant. *See* 510(k) Substantial Equivalence Determination Decision Summary, 510(k) Number k110035, https://www.accessdata.fda.gov/cdrh_docs/reviews/K110035.pdf [Ex. 5] (last accessed Feb. 9, 2021) (identifying Thermo Fisher Scientific Oy as the 510(k) applicant).[4] It is a "fully automated random access analyzer used to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used." *Id.*

Under the contract with DOCCS, Microgenics also agreed to supply immunoassays and testing reagents for use in the Indiko Plus analyzers. Contract No. CC161458 [Ex. 2], App. C, at 25. As set forth in the contract, DOCCS, not Microgenics, identified the specific substances for

[4] The Court may consider the publicly available FDA market-clearance documents for the subject products. *See, e.g.*, *Crespo v. S.C. Johnson & Son, Inc.*, 394 F. Supp. 3d 260, 266 n.3 (E.D.N.Y. 2019) (taking judicial notice of documents on EPA's website, including records pertaining to the subject product's EPA registration); *Tierney v. AGA Med. Corp.*, No. 4:11CV3098, 2011 WL 7400469, at *4 (D. Neb. Nov. 18, 2011) (taking judicial notice of "Instructions for Use" documents publicly available on FDA's website where said documents contained warnings against same adverse reaction suffered by plaintiff).

which it required reagents and the estimated annual quantity. *Id.* at 25, 28–29. DOCCS's list of target substances included buprenorphine, which is the target substance at issue in this case. *Id.* at 28.

As with any immunoassay urine drug screen, the buprenorphine immunoassay Microgenics supplied to DOCCS "provides only a preliminary analytical test result." 510(k) Substantial Equivalence Determination Decision Summary, 510(k) Number k163101, at 2 https://www.accessdata.fda.gov/cdrh_docs/reviews/K163101.pdf [Ex. 6] (last accessed Feb. 5, 2021). The Indications for Use ("IFU") convey that information explicitly. *Id.*; *accord* Compl. ¶ 58. The IFU also advises that, in the event of a positive screen, a "more specific alternative chemical method must be used to obtain a confirmed analytical result." *Id.* "Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method." *Id.* The IFU further cautions users that "[c]linical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used." *Id.*

The contract between Microgenics and DOCCS identified specific, targeted training that Microgenics was to provide to DOCCS personnel regarding the use and operation of the equipment supplied under the contract. In particular, Microgenics was required to give basic proficiency and certification training to five DOCCS employees at each of the fifty-two DOCCS facility locations, including how to order reagents, relevant part numbers, and cross-reactivity considerations. Contract No. CC161458, App. H, at 2. Microgenics also agreed to present certain additional "master training" classes approximately once per year addressing current drug trends, equipment maintenance, ordering part numbers, and cross-reactivity. *Id.*

The contract also included limited product-support and maintenance services. The express language of the contract outlined approximately once-per-year preventive-maintenance visits and as-needed customer support in the form of a 24/7 support hotline:

- This bid comes with a maintenance agreement for the life of the agreement during 8-5pm Monday –Friday (no weekend or state holidays). The service agreement covers the following:
  - 24/7 telephone support.
  - Preventive maintenance was determined based on National studies of meantime between failure to only need 1 PM /year.
  - Will provide a 24-hour Response time after onsite service is determined to be needed.
  - All travel, parts and labor are no at no additional charge for the repair of the instrument excluding acts of clear undeniable sabotage (hammer to the instrument, spray paint etc.) or acts of nature (i.e. a roof falling in on instrument)
  - If a replacement instrument is required due to engineer report, a replacement will be received by 48 hours in best case not including any weather-related shipping delays.
  - Software replacement if determined is necessary, will be shipped as soon as possible with best case 24- 48 hours not including any shipping delays. We will replace the instrument or the software which ever can be done faster so that you are not impacted.
  - Microgenics offers 24/7 helpdesk assistance 365 days a year
  - Microgenics welcomes feedback and any feedback would be directed through local sales rep.
  - Microgenics instrument comes with a warranty
  - Should an instrument or part return be necessary, no additional cost would occur.

Contract No. CC161458, App. H, at 2–3.

E. Plaintiff's drug screen and contested drug charge

Plaintiff claims he received a random urine screening on March 28, 2019, using an Indiko Plus urinalysis analyzer. Compl. ¶ 94. The sample screened positive for buprenorphine. *Id.* ¶ 95. Despite the positive screening result, Plaintiff insists the results were not accurate. *Id.* ¶ 97. DOCCS did not confirm Plaintiff's positive result through a second testing method, contrary to the IFU and despite Plaintiff's request for confirmatory testing. *Id.* ¶ 98.

Plaintiff claims that after he screened positive, DOCCS rendered a disciplinary disposition against him. *Id.* ¶ 99. Plaintiff was sentenced to thirty days keeplock, suspended for sixty days, and received a referral to the Temporary Release Committee. *Id.* ¶ 100. Plaintiff alleges he was

also removed from eligibility for presumptive parole. *Id.*¶ 102. Plaintiff was released on August 12, 2019. *Id.* ¶ 115.

F. Plaintiff's Complaint

Plaintiff alleges that, by virtue of its contract with DOCCS, Microgenics owed him a duty "to ensure that the Indiko Plus urinalysis analyzers were used in accordance with applicable standards and produced accurate and reliable test results." Compl. ¶ 118. The "applicable standards" to which Plaintiff seemingly refers are paraphrases of statements set forth in Microgenics' IFU—that testing by immunoassay "should be used as an initial screen only" and that "confirmatory testing is required to verify any positive result." *Id.* ¶¶ 57–58. Plaintiff alternatively alleges that Microgenics somehow failed to conduct adequate development testing and to give appropriate warnings for an acceptable degree of cross-reactants related to its immunoassays. Compl. ¶ 64–67, 69, 71

Plaintiff claims that Microgenics breached its alleged duty to inmates by failing to ensure that Indiko Plus analyzers "yielded accurate and reliable test results"; by entering into a contract for the "use" of its analyzers that "was inconsistent with applicable standards"; by "failing to train DOCCS employees on applicable standards"; "failing to disclose" that it had "not properly tested the Indiko Plus with the Buprenorphine Assay II"; and by "testifying at disciplinary hearings . . . when [it] knew that the results were a preliminary screen only." Compl. ¶ 119. In particular, Plaintiff avers that the equipment supplied by Microgenics was "far too inaccurate" for use by DOCCS, and thereby contributed to a high volume of alleged false positive drug screen results for inmates incarcerated by DOCCS. *Id*. ¶¶ 70–73. Plaintiff claims that due to the alleged false positives generated by the Indiko Plus urinalysis analyzers used by DOCCS, approximately 2,000 incarcerated people received disciplinary actions based on unreliable drug screens. *Id.* ¶ 80. Plaintiff alleges that based on the purported rate of false positives, DOCCS overturned every

positive result for the specified substances tested using the supplied equipment, and subsequently terminated its contract with Microgenics regarding the same. *Id.* ¶¶ 75–77.

Plaintiff seeks to recover alleged damages for the "loss of liberty, emotional and physical pain and suffering caused by the extended incarceration, and humiliation at being falsely accused of being an illegal drug user." *Id.* ¶ 121.

III. LAW AND ARGUMENT

A. The Complaint fails to state a plausible claim for relief and should be dismissed.

To withstand a motion to dismiss under Rule 12(b)(6), "'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Concord Assocs., L.P. v. Entm't Props. Trust*, 817 F.3d 46, 52 (2d Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2007)). The plausibility standard requires "'more than a sheer possibility that a defendant has acted unlawfully.'" *Galiano v. Fidelity Nat'l Title Ins. Co.*, 684 F.3d 309, 313 (2d Cir. 2012) (quoting *Iqbal*, 556 U.S. at 678). To meet the standard, a plaintiff must plead "'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Anyachebelu v. Brooklyn Hosp. Ctr.*, No. 16 Civ. 3159 (DLI) (VMS), 2017 WL 9511073, at *4 (E.D.N.Y. July 20, 2017) (quoting *Iqbal*, 556 U.S. at 678).

Although courts "construe the pleadings liberally, 'bald assertions and conclusions of law will not suffice.'" *Spool v. World Child Int'l Adoption Agency*, 520 F.3d 178, 183 (2d Cir. 2008) (quoting *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996)). Nor will a "'formulaic recitation of the elements of a cause of action.'" *Anyachebelu*, 2017 WL 9511073, at *4 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The "factual allegations must be enough to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Port Dock &*

Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 121 (2d Cir. 2007) (citing *Twombly*, 550 U.S. 544).

1. The Complaint fails to state a claim because it does not plausibly allege that Microgenics owed a duty directly to Plaintiff.

Under New York law, to establish a claim for negligence, "'a plaintiff must demonstrate (1) a duty owed by the defendant to the plaintiff, (2) a breach thereof, and (3) injury proximately resulting therefrom.'" *Pasternack v. Lab. Corp. of Am. Holdings*, 27 N.Y.3d 817, 825 (2016) (quoting *Solomon v. City of N.Y.*, 66 N.Y.2d 1026, 1027 (1985)).

The threshold question in any negligence action is whether a defendant owes a "legally recognized duty of care to [a] plaintiff." *Stephanie L. v. House of the Good Shepherd*, 186 A.D.3d 1009, 1011 (4th Dep't 2020). "Absent a duty running directly to the injured person there can be no liability in damages, however careless the conduct or foreseeable the harm." *532 Madison Ave. Gourmet Food v. Finlandia Ctr.*, 96 N.Y.2d 280, 289 (2001). "To establish the existence of a legal duty, the injured party must show that a defendant owed not merely a general duty to society but a specific duty to him or her …." *Stephanie L.*, 186 A.D.3d at 1011. (quotations and citations omitted).

Duties can arise out of different types of relationships, but under New York law, mere foreseeability of injury does not create a duty of care. *R.M. Bacon, LLC v. Saint-Gobain Performance Plastics Corp.*, 959 F.3d 509, 516 (2d Cir. 2020) ("[T]he mere fact of foreseeability of harm does not define duty."). That limitation on liability "is necessary to avoid exposing defendants to unlimited liability to an indeterminate class of persons conceivably injured by any negligence in a defendant's act." *Finlandia Ctr.*, 96 N.Y.2d at 289. And it is "'the responsibility of the courts in fixing the orbit of duty, to limit the legal consequences of wrongs to a controllable

degree and to protect against crushing exposure to liability.'" *McCarthy v. Olin Corp.*, 119 F.3d 148, 157 (2d Cir. 1997) (quoting *Strauss v. Belle Realty Co.*, 65 N.Y.2d 399, 402 (1985)).

Here, Plaintiff alleges a duty predicated on Microgenics' alleged responsibilities under its contract with DOCCS. *E.g.*, Compl. ¶¶ 56, 119. But New York courts "have as a general policy and approach declined to leapfrog duties, over directly juridically related parties, to noncontractaually related" parties. *Milliken & Co. v. Consol. Edison Co. of N.Y., Inc.*, 84 N.Y.2d 469, 477 (1994) (citation omitted). Thus, when a plaintiff premises a negligence claim on a contractual commitment to someone other than the plaintiff, the general rule is that the undertaking "is ***not*** a source of tort liability to third parties." *Landon v. Kroll Lab. Specialists, Inc.*, 22 N.Y.3d 1, 6 (2013) (emphasis added). As courts in this district have explained, "a contractual agreement between two parties will rarely create a duty in tort that extends to a non-promisee." *Doona v. OneSource Holdings, Inc.*, 680 F. Supp. 2d 394, 402 (E.D.N.Y. 2010); *accord Nguyen v. Morrison Healthcare*, 412 F. Supp. 3d 196, 202 (E.D.N.Y. 2018) ("Under New York law, 'a contractor generally does not owe an independent duty of care to a non-contracting third party.'" (citing *Guzman v. Wackenhut Corp.*, 394 F. App'x 801, 803 (2d Cir. 2010))).

There are exceptions, of course. For example, when a contract is for the sale of goods, the product seller owes the product's users a duty of reasonable care to ensure the product is not defective in regard to safety—that is, a duty to ensure the product is not "reasonably certain to be dangerous." *Nealy v. U.S. Surgical Corp.*, 587 F. Supp. 2d 579, 583 (S.D.N.Y. 2008). That duty is inapplicable here, however, because Plaintiff has not asserted a claim for products liability.

As to services contracts, the New York Court of Appeals has identified three "narrow circumstances" in which a contractual undertaking gives rise to a duty to third parties. *Santos v. Deanco Servs., Inc.*, 142 A.D.3d 137, 140 (2d Dep't 2016). Specifically, a tort duty arises (1)

where the contracting party launches a force of harm, (2) where the plaintiff detrimentally relies on the continued performance of the contract party's duties, or (3) where the contracting party has entirely displaced the other party to maintain premises safely. *Espinal v. Melville Snow Contractors*, 98 N.Y.2d 136, 140 (2002).

Plaintiff bears the burden to expressly plead the applicability of any *Espinal* exceptions and any requisite facts to support the same. *Graef v. Ricoh, USA, Inc.*, Civ. No. 1:17-CV-1105 (DJS), 2020 WL 950282, at *3 (N.D.N.Y. Feb. 27, 2020). Plaintiff has not done so here, but he apparently seeks . . . , Plaintiff does not affirmatively plead any of the three so-called "*Espinal* exceptions," but he apparently seeks to invoke the force-of-harm exception as applied in *Landon v. Kroll Laboratory Specialists, Inc. See* Pl.'s Letter to Cogan, B. [ECF 21], at 1–2. On the facts alleged, however, the force-of-harm exception does not apply either.

In *Landon v. Kroll Laboratory Specialists, Inc.*, the New York Court of Appeals considered whether a tort duty arises under the *Espinal* force-of-harm exception in the event of an allegedly inaccurate drug test. 22 N.Y.3d 1, 6–7. The plaintiff there alleged that his probation officer required him to provide an oral fluid sample, which was sent to a drug-test laboratory for testing. *Landon*, 22 N.Y.3d at 48. The lab generated a report stating that the plaintiff's sample tested positive for THC, *id.*, and although a contemporaneous blood test the plaintiff independently ordered came back negative, the county probation department commenced violation-of-probation proceedings that extended the plaintiff's probation. *Id.* The plaintiff sued the laboratory for negligence, alleging that it violated multiple established industry and government standards for laboratory drug testing, including a federal standard for the test cutoff level, a state standard requiring chromatographic confirmatory testing, and a proposed federal guideline that a urine sample should be taken contemporaneously with an oral sample. *Id.* at 4–5.

Analyzing those allegations in view of the general no-duty rule, a divided Court of Appeals held that the complaint stated a viable claim for relief under the force-of-harm exception. *Landon*, 22 N.Y.3d at 5. Noting that laboratories are "in the best position to prevent false positive results," the court concluded that laboratories owe a tort duty directly to test subjects to conduct tests "***in keeping with relevant professional standards***." *Id.* at 6–7 (emphasis added).

The *Landon* holding does not, however, establish a broad duty running from any drug-screen services provider to drug-screen subjects. To the contrary, and as the New York Court of Appeals has explained, *Landon* is a "limited ruling." *Pasternack v. Lab. Corp. of Am. Holdings*, 27 N.Y.3d 817, 826 (N.Y. 2016). The tort duty recognized there is narrowly "limited to 'th[o]se circumstances'" in which a "drug laboratory[ ]" fails to "adhere to professionally accepted scientific testing standards in the testing of the biological sample." *Id.*

Here, the Complaint further fails to state a claim under *Landon* because the facts Plaintiff alleges differ from those at issue in *Landon* in at least two critical and decisive respects.

a. Microgenics is not a "drug laboratory."

First, Microgenics did not provide laboratory drug-test services to DOCCS. It supplied drug-screening equipment and training on how to use the equipment, but the drug screens themselves were performed by DOCCS personnel. That distinction is dispositive under *Landon*. In choosing to recognize a limited tort duty as to drug laboratories, the New York Court of Appeals emphasized that a drug-testing laboratory is "in the best position to prevent false positive results." 22 N.Y.3d at 6–7. The same cannot plausibly be said about a contractor that supplies products and related support services for in-house urinalysis drug screens but that does not obtain the urine sample, store the urine sample, or process the urine sample—and that does not have continuous possession of, or even access to, the analyzers, immunoassays, and other products used to conduct the screens. Microgenics may have supplied equipment that could be *used* in a laboratory, but it is

not itself a laboratory. *See* N.Y. Pub. Health Law § 571(1) (defining a "clinical laboratory" as a "facility" for certain types of examinations of materials derived from the human body); Compl. ¶ 8 (alleging that Microgenics specializes "in the development, manufacture, marketing, and sale of products relating to clinical diagnostics").

To the extent any laboratory-like services were performed under the present circumstances, they were provided by DOCCS, and it was DOCCS that was "in the best position to prevent false positive results." As alleged, the facts are clear: Plaintiff's drug screening was conducted by a DOCCS employee, in a DOCCS facility, as part of Plaintiff's incarceration in DOCCS's custody, and the resulting disciplinary action was administered by DOCCS. Compl. ¶ 99; *see also* Pl.'s Letter to Cogan, B. [ECF 21], at 2 (acknowledging actual testing was performed by DOCCS correction officers working inside DOCCS prisons). Microgenics' involvement in providing training and certification on the use of its equipment, or the related presence of a Microgenics employee conducting training at the time Plaintiff's sample was screened, does not transform its limited role as an equipment provider into that of a drug-test laboratory.

b. Plaintiff does not allege any "relevant professional standards."

Second, the limited duty recognized in *Landon* is that a laboratory must perform drug tests in keeping with "professionally accepted scientific testing standards." *Pasternack*, 27 N.Y.3d at 826. So even if *Landon* were extended to apply to entities other than drug-test laboratories, a plaintiff could plead a colorable claim against such entities only by identifying a "statutory, regulatory, or professional standard[ ]" with which the defendant allegedly failed to comply. *Braverman v. Bendiner Schlesinger, Inc.*, 121 A.D.3d 353, 359 (2d Dep't 2014). For example, in *Landon*, the relevant standard was an explicitly pleaded screen test cutoff level recommended by the United States Department of Health and Human Services Substance Administration (SAMHSA) and to which the testing laboratory failed to adhere. *Landon*, 22 N.Y.3d at 2

(comparing SAMHSA 4.0 ng/ml standard cited in complaint to significantly lower 1 ng/ml used by defendant).

Here, Plaintiff cites no such standards. Indeed, he does not allege the existence of even a single relevant professionally accepted scientific testing standard. Although the Complaint repeatedly refers to "applicable standards," Plaintiff offers nothing more than scattershot allegations that wholly fail to rise to the level of a requisite scientific or professional standard.

The only alleged standards that Plaintiff directly identifies are Microgenics' admonitions to product users that drug screens by immunoassay generate preliminary analytical results and that more specific alternative chemical methods must be used to obtain confirmed analytical results. Compl. ¶¶ 57–58. Those statements from Microgenics' IFU are not scientific testing *standards* that governed Microgenics' contractual undertaking; they are *descriptions* of the type of products DOCCS chose to purchase—immunoassay drug screens that produce preliminary analytical results that must be confirmed chromatographically.

Alternatively, Plaintiff appears to argue that Microgenics failed to adhere to some otherwise unidentified professional or scientific standard based on an alleged failure to adequately test for cross-reactants. Plaintiff repeatedly alleges that Microgenics somehow failed to conduct adequate development testing and to give appropriate warnings for an acceptable degree of cross-reactants related to its immunoassays. Compl. ¶ 64–67, 69, 71. But here again, Plaintiff cites no relevant professionally accepted standard by which to assess what cross-reactants, if any, Microgenics should have tested for prior to releasing the subject products. Plaintiff's cherry-picked selection of certain over the counter medications, *see* Compl. ¶ 65, does not establish a professionally accepted scientific standard. Rather, Plaintiff merely contends that *all* medications seemingly should have been tested for, without any scientific or professional standard underlying

that contention. Plaintiff's own self-serving propositions are not sufficient to satisfy the requirements set forth by *Landon*.

Plaintiff therefore has not plausibly alleged a relevant professionally accepted scientific standard governing Microgenics' contractual obligations to DOCCS, and the Complaint thus fails to state a claim under *Landon*. *See Pasternack*, 27 N.Y.3d at 826 (holding that ministerial standards governing laboratory-test services providers do *not* create tort duties owed directly to third-party test subjects); *Braverman*, 121 A.D.3d at 359 (holding that the plaintiffs had no claim under *Landon* because there were "no professional standards implicated in this case").

In sum, Plaintiff has not alleged facts sufficient to overcome the general no-duty rule set forth in *Espinal*.

2. Even if Plaintiff had alleged an actionable duty, he has not plausibly alleged that Microgenics breached any such duty.

To plead a claim for negligence, a plaintiff "is required to allege . . . 'how the [defendant] was negligent.'" *Farash v. Cont'l Airlines, Inc.*, 337 F. App'x 7, *9 (2d Cir. 2009) (alteration in original) (citing *Patterson v. New York*, 54 A.D.2d 147, 150 (4th Dep't 1976)). Conclusory allegations of breach do not suffice. *Id.* In particular, breach under *Landon* requires violation of a professionally accepted testing standard. *Landon*, 22 N.Y.3d at 6. As noted, however Plaintiff has utterly failed to identify the existence of *any* relevant professional, scientific, or regulatory standard, let alone the violation of such a standard.

Assuming the truth of his averments and granting him every favorable inference, Plaintiff has not adduced sufficient allegations to state a plausible negligence claim, and his action must be dismissed.

IV. CONCLUSION

Plaintiff's sole negligence claim against Microgenics is predicated on an alleged duty derived from Microgenics contract with DOCCS to supply certain drug screen equipment. However, Plaintiff has failed to plausibly allege any facts to circumvent the general rule that contractual obligations do not give rise to tort duties owed to noncontractual third parties. Specifically, Plaintiff has failed to plausibly allege Microgenics is a "laboratory" as required under *Landon* and has likewise failed to identify any relevant professional, regulatory, or scientific standard. Accordingly, Plaintiff has failed to plausibly allege that Microgenics owed him a duty or that Microgenics breached any purported duty. For those reasons, Defendant Microgenics respectfully requests the Court grant its motion to dismiss the Second Amended Complaint.

Respectfully submitted,

Dated: February 10, 2021

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